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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,691	06/20/2003	Jean-Pierre Sommadossi	06171.IDX 1007 CON1	1388
57263	7590	10/07/2008		
KING & SPALDING LLP 1180 PEACHTREE STREET ATLANTA, GA 30309			EXAMINER MCINTOSH III, TRAVISS C	
			ART UNIT	PAPER NUMBER
			1623	
			MAIL DATE	DELIVERY MODE
			10/07/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/602,691	<b>Applicant(s)</b> SOMMADOSSI ET AL.	
	<b>Examiner</b> TRAVISS C. MCINTOSH III	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 130-139, 141-152 and 161-171 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 130-139, 141-152, 161-171 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

The Amendment filed 6/25/2008 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 130-133, 137-138, and 141-143 have been amended.

Claims 161-171 have been added.

Claims 1-129, 140, and 153-160 have been canceled.

Remarks drawn to rejections of Office Action mailed 2/26/2008 include:

Double Patenting Rejections: which has been maintained in part for reasons of record.

Claim objections: which have been overcome by applicant's amendments and have been withdrawn.

An action on the merits of claims 130-139, 141-152, and 161-171 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

#### ***Double Patenting***

The provisional rejection of claims 130, 132-139, 141-146, and 150-152 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-3, 8-17, and 19-67 of copending Application No. 11/005,466 is withdrawn as the '466 application has been abandoned.

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The provisional rejection of claims 130-131, 137-139, and 141-149 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11, 12, 17-25, and 43-65 of copending Application No. 10/609,298 is maintained for reasons of record. Newly added claims 161-162, 164, and 166-170 are rejected for the same reasons. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating HCV by administering pyrimidine 2'-methyl-ribofuranosyl nucleosides using the same forms of compositions in the same patients. It is obvious that the instant application and the '298 application are substantially overlapping.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted applicants argued that since the only rejections left are provisional rejections, then the case should be issued according to MPEP 804, subsection I.B. However, since there are still pending rejections, this is not found persuasive.

The provisional rejection of claims 130-131, 137-139, and 141-149 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-3, 8-17, and 19-52 of copending Application No. 11/005,440 is withdrawn as the '440 application has been abandoned.

The provisional rejection of claims 130-131, 133-139, and 141-149 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-17 and 19-66 of copending Application No. 11/005,443 is maintained for reasons of record. Newly added

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claims 161-162, 164, and 166-170 are rejected for the same reasons. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating HCV by administering pyrimidine 2'-methyl-ribofuranosyl nucleosides, optionally in combination with additional antiviral agents, using the same forms of compositions in the same patients. It is obvious that the instant application and the '443 application are substantially overlapping.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted applicants argued that since the only rejections left are provisional rejections, then the case should be issued according to MPEP 804, subsection I.B. However, since there are still pending rejections, this is not found persuasive.

The provisional rejection of claims 130, 132-139, 141-146, and 150-152 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-17 and 19-68 of copending Application No. 11/005,444 is maintained for reasons of record. Newly added claims 161, 163, 165-169, and 171 are rejected for the same reasons. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating HCV by administering purine 2'-methyl-ribofuranosyl nucleosides and optionally in combination with another antiviral agent, using the same forms of compositions in the same patients. It is obvious that the instant application and the '444 application are substantially overlapping.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted applicants argued that since the only rejections left are provisional rejections, then the case should be issued according to MPEP 804, subsection I.B. However, since there are still pending rejections, this is not found persuasive.

The provisional rejection of claims 130-131, 133-139, and 141-149 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 3, 8-17 and 19-57 of copending Application No. 11/005,446 is withdrawn as the '446 application has been abandoned.

The rejection of claims 130-131, 137-139, and 141-149 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of US Patent No. 6,812,219 is maintained for reasons of record. Newly added claims 161-162, 164, and 166-170 are rejected for the same reasons. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating viruses from the Flaviviridae family (HCV in the instant application and flavivirus or pestivirus infections in the '219 patent) by administering pyrimidine 2'-methyl-ribofuranosyl nucleosides using the same forms of compositions in the same patients. It is obvious that the instant application and the '219 patent are substantially overlapping.

It is noted applicants filed a terminal disclaimer to overcome this rejection, however, this terminal disclaimer has been DISAPPROVED pursuant to the assignee clauses on the terminal

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disclaimers. While the terminal disclaimers state that they are each less than the entire right, title and interest, there is nothing showing 100% ownership of the right, title and interest has supplied terminal disclaimers. Applicants should file terminal disclaimers as they did in the instant application on 10/6/2006. If a TD is filed, or in this situation 2 TD's and applicants state that they are the assignees of less than the entire right, title, and interest, then applicants are not asserting that they have 100% and the TD is improper. See 37 CFR 1.321(b)(3).

The rejection of claims 130, 132-139, 141-146, and 150-152 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-42 of US Patent No. 7,148,206 is maintained for reasons of record. Newly added claims 161, 163, 165-169, and 171 are rejected for the same reasons. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating viruses from the Flaviviridae family (HCV in the instant application and flavivirus or pestivirus infections in the '206 patent) by administering purine 2'-methyl-ribofuranosyl nucleosides and optionally in combination with another antiviral agent, using the same forms of compositions in the same patients. It is obvious that the instant application and the '206 patent are substantially overlapping.

It is noted applicants filed a terminal disclaimer to overcome this rejection, however, this terminal disclaimer has been DISAPPROVED pursuant to the assignee clauses on the terminal disclaimers. While the terminal disclaimers state that they are each less than the entire right, title and interest, there is nothing showing 100% ownership of the right, title and interest has supplied terminal disclaimers. Applicants should file terminal disclaimers as they did in the instant

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application on 10/6/2006. If a TD is filed, or in this situation 2 TD's and applicants state that they are the assignees of less than the entire right, title, and interest, then applicants are not asserting that they have 100% and the TD is improper. See 37 CFR 1.321(b)(3).

The rejection of claims 130-139 and 141-152 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of US Patent No. 7,105,493 is maintained for reasons of record. Newly added claims 161-171 are rejected for the same reasons. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating viruses from the Flaviviridae family (HCV in the instant application and flavivirus or pestivirus infections in the '493 patent) by administering purine and pyrimidine 2'-methyl-ribofuranosyl nucleosides and optionally in combination with another antiviral agent, using the same forms of compositions in the same patients. It would be obvious to use the method of treating a flavivirus in treating HCV, and visa-versa. It is obvious that the instant application and the '493 patent are substantially overlapping.

It is noted applicants filed a terminal disclaimer to overcome this rejection, however, this terminal disclaimer has been DISAPPROVED pursuant to the assignee clauses on the terminal disclaimers. While the terminal disclaimers state that they are each less than the entire right, title and interest, there is nothing showing 100% ownership of the right, title and interest has supplied terminal disclaimers. Applicants should file terminal disclaimers as they did in the instant application on 10/6/2006. If a TD is filed, or in this situation 2 TD's and applicants state that they are the assignees of less than the entire right, title, and interest, then applicants are not asserting that they have 100% and the TD is improper. See 37 CFR 1.321(b)(3).



***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRAVISS C. MCINTOSH III whose telephone number is (571)272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss McIntosh  
September 30, 2008  
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/Traviss C McIntosh III/  
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